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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,593	03/30/2004	Bernard Andreas	021629-002500US	5895

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,593	ANDREAS ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In this case, the disclosure of the prior-filed application, Application No. 10/637,713, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior filed application provides support for a multiple stent delivery device as in Figs. 1-2b and 7a-8. The prior filed application further provides support for stent segments (placed in a main branch) having side wall openings that can be expanded by a balloon dilation catheter where a catheter can be used to place stents in the side branch. However there is no support for using the multiple stent delivery device in a method of delivering a first stent to a main branch and delivering a second stent to a side branch. The only mention of delivering stents to a side branch is paragraphs [0100] and [0104] in the '713

application, which is where applicant points to for support of the claimed invention. However, close inspection of these paragraphs (or anywhere else in the specification) does not indicate that the delivery catheter that is used to place the first stent in the main branch is the same delivery catheter that is used to place the second stent in the side branch as required by claims 53 and 64. For example Paragraph [0100] states "*a balloon dilatation catheter may be positioned through a circumferential slot 104 and expanded*," and "*a catheter may be inserted through stent segment 32 and into the side branch for placing stents*".

Therefore the effective filing date for the purposes of applying art will be the filing date of the instant application, 03/30/2004.

Claim Objections

2. Claims 53 and 64 are objected to because of the following informalities: Claims 53 and 64 state that the stents are "unconnected with each other" but later states that the "stents are in direct engagement with one another when unexpanded". Since "connected" is usually interpreted in a similar manner as "engaged", the choice o f terminology could use clarification as to what structure constitutes "unconnected" to distinguish it from being interpreted as "unengaged". It can be interpreted from the specification that the stents (stent segments) are "engaged" as in touching or in contact with each other and at the same time "unconnected" as in not fixedly or rigidly attached. Appropriate correction is required.

Claim Rejections - 35 USC § 112 First

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 57, 69-70, 73-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 53 and 64 recite "expanding the first and second stent concurrently in the main branch". The specification (at Figs. 6a-6H and paragraphs [0054-0059] describe the step of deploying multiple segments (172) at a time of a first stent (170) (specifically at Para [0057]). The specification goes on to describe delivering a second stent in the branch or a third stent in the main branch after moving the catheter (specifically at Para [0058-0059]). It is clear that the only elements that are deployed concurrently are the stent segments (172) and thus the claimed first stent is interpreted as a first segment and the claimed second stent is a second segment. Since they are expanded concurrently, together the first segment and the second segment make up what is disclosed as a stent.

5. Claims 57 and 70 which are dependent from claims 53 and 64 respectively recite that the first and second stents (interpreted as stent segments above) have a different overall length than the third stent. However there is no disclosure that the stent

segments have different lengths or that one would choose to use stent segments with different lengths together. Rather there is only disclosure that choosing different numbers of segments results in a stent having a different overall length (Para [0058]).

6. Claims 73-75 and 76-78 are dependent form claims 56/53 and 71/64 respectively. Claims 56 and 71 further define the claimed stents (disclosed stent segments as interpreted above) as having separable segments. The only separable segments on each stent segment would be the struts which are separable when the stent segments are expanded. Claims 73 and 76 further require that the first and second stent (stent segments) have a segment (strut) with a first length and the third stent (stent segment) has a segment (strut) with a different length. However there is no disclosure that the stent segments (struts) of each stent (stent segment) have different lengths or that one would choose to use stent segments having struts with different lengths. Further, there is no disclosure that the stent segments (struts) of each stent (stent segment) have a length that substantially traverses the lesion.

7. Claims 69 and 70 which are dependent from claim 64 recite that the first stent (stent segment as interpreted above) has a different geometry or a different length than the second stent (stent segment). However there is no disclosure that the stent segments have different lengths or geometries or that one would choose to use stent segments with different lengths or geometries together. Rather there is only disclosure that choosing different numbers of segments results in a stent having a different overall length (Para [0058]).

Claim Rejections - 35 USC § 112 Second

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 53, 57, 72-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 53 recites the limitation "two of the stents" in line 8. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether “two of the stents” refers back to “a plurality of stents” in line 4 or back to “a first, second and third stent" in line 4.

11. Claim 57 recites that the “first and second stents have a different overall length than the third stent. It is unclear if the overall length applies to each of the first and second stent or if it applies to the overall length of the two stents together.

12. Claims 73 and 76 recites that a first number of separable segments comprise a segment of each of the first and second stents. But the first and second segments are the separable segments (se explained above with respect to the 112 First rejections). Further based on examiner’s interpretation that the separable segments are the struts, it is unclear how the struts have a first length that substantially traverses the lesion.

13. Claim 72 recites “expanding one of the expandable openings of the third stent that is aligned with the branch vessel". There is insufficient antecedent basis for this limitation in the claim. Thus it is unclear what expandable opening is aligned with the branch.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 53, 54, 56-62, 64, 65, 67, 69-71 and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0793873) in view of Poncet (US 5,833,694) and further in view of Brucker (US 2002/0793873).

16. With respect to claims 55 and 64, Chermoni discloses a method of treating one or more lesions in a vessel, the vessel, the method comprising: providing a plurality of stents comprising a first, second and third stent unconnected with each other (206a, 206b, 206c) positioning a delivery catheter (Fig. 11) in the main branch, the delivery catheter having an expandable member (704) disposed thereon, wherein one stent is positioned over the expandable member (Fig. 12); radially expanding the expandable member thereby radially expanding the first stent in the main branch; positioning the delivery catheter at a different location; and radially expanding the expandable member thereby radially expanding the third stent; wherein the delivery catheter remains in the vessel between radially expanding the first and third stents (Para [009]); Claim 56 and 71: the first and second and third stents each comprise a plurality of separable segments (where the segments are struts which are separable upon expansion of the stent); Claims 57 and 70 the first and second stents has a different length than the third

stent (Para [0005]; [0047]); Claims 58 and 59: the first and second stent can be deployed before the third stent or the third stent can be deployed before the first and second stent (Para [0049]); Claim 61 and 62: adjusting the length of the first and second or third stent before deploying the first and second or third stent while the delivery catheter remains in the vessel (Para [0008] states that the stents may be delivered in any order and may be different lengths and so the lengths are adjusted by choosing a different order of stents); Claims 73 and 76: selecting a first number of separable segments for radial expansion and selecting a second number of separable segments for radial expansion different from the first (where all the separable segments (i.e. struts) would be chosen and would be different since stents are different sizes); Claims 74, 75, 77 and 78: the step of selecting comprises moving a sheath or a pusher tube (where 114 can be a sheath or a pusher tube).

17. Chermoni does not disclose that the stents positionable (capable of being positioned) over the expandable member in direct engagement with one another when unexpanded. However Poncet discloses a multiple stent delivery device where the stents are in direct engagement with each other when unexpanded (Fig. 1a). Poncet also discloses a similar embodiment with spacers between the stents similar to that of Chermoni. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Chermoni such that the stents engage one another when unexpanded. Poncet shows that the two structures were art recognized equivalents at the time of the invention was made, and so, one of ordinary skill in the art would have found it obvious to substitute one for the other, since substitution of one

known element for another would have yielded predictable results, namely an efficient way of delivering multiple stents.

18. Chermoni modified by Poncet does not disclose the step of radially expanding the first and second stent concurrently. However, Richter (US 2002/107560) teaches a single stent device having multiple stent segments ((2) as in Fig. 4) whereby the segments are unconnected with each other (after the stent is deployed) (Fig . 4). The detached stent segments achieve the advantage of providing the radial strength of a unitary stent without the added longitudinal rigidity that causes trauma to the vessel (Para [004-006]. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of detachable stent segments (such that one segment is the first stent and the other segment is the second stent) into the method and device of modified Chermoni in order to achieve the advantage thereby meeting the limitation that the first and second stent are expanded concurrently. The further limitations of the second stent in the dependent claims would still apply as stated above. With respect to claim 54, a second detachable stent in place of the aforementioned second or third stent of Chermoni would meet the limitations of a third and fourth stent in the side branch.

19. Chermoni modified by Poncet and Richter does not disclose a method that incorporates delivering a third stent to a side branch or that the delivery catheter is positioned through an opening in a sidewall of the first or second stent to deploy the third stent. However, Brucker discloses a method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main

branch at a bifurcation, the method comprising similar steps to those that are disclosed by modified Chermoni such as positioning the delivery catheter at multiple lesions and expanding first and second stents at different locations without removing the catheter from the body. [Note that while the disclosure of Brucker indicates a second stent, in light of the modification by Richter, the second stent of Brucker is treated as the claimed third stent and the first stent is treated as the claimed first and second stent]. Brucker further discloses with respect to claims 53 and 64 positioning a delivery catheter (112) in the main branch, and radially expanding the expandable member thereby radially expanding a first (and second) stent (94 or 114) in the main branch across the bifurcation (Fig. 13, 14, 17 and 18; Para [0083]); positioning the delivery catheter in the side branch and radially expanding an expandable member (120) thereby radially expanding a third stent (74 or 116) in the side branch (Fig. 10-12, 20, Para [0084]); wherein the delivery catheter is not removed from the vessel between deploying the first (and second) and third stents (see Figs. 18-20; Para [0084]); With respect to claim 55: the delivery catheter is positioned through an opening (16) in a sidewall of the first (or second stent) to deploy the third stent (Fig. 20); Claim 60: wherein the first stent and the third stent each have a portion in the main branch. (Fig. 14, 16, 17); Claim 65: dilating an opening in the first (or second) stent by expanding the expandable member on the delivery catheter (Fig. 20 when the stent is expanded); Claim 67 wherein the first (or second) stent has a first portion with a plurality of first slots (for example at scaffold 14) and a second portion with a plurality of second slots (openings formed by mesh pattern in rest of stent), the first slots being larger than the second slots; Claim 69: wherein the

first stent has a different geometry than the second stent (the first stent has a side opening) (in light of the 112 rejection the second stent is being interpreted as the third stent).

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the method of treating a bifurcated vessel into the method and apparatus of modified Chermoni. Both modified Chermoni and Brucker disclose similar devices for multiple stent delivery. Brucker discloses an additional method of delivering the multiple stents to lesions in a bifurcated vessel having a main vessel and a branch vessel. One of ordinary skill would have been capable of applying this known technique of enhancement (delivering stents to a bifurcated vessel) to a base device (multiple stent delivery catheters) in order to yield predictable results namely providing an efficient way of delivering multiple stents to multiple lesions at a bifurcation. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

21. Claims 55, 66, 68, 72, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) in view of Poncet, Richter and Brucker et al. (US 2002/0193873) as applied to claims 53 and 64 above and further in view of Fischell (US 5,697,971).

22. Modified Chermoni discloses a method of treating a lesion in a bifurcation but does not disclose that the first and second stent (taught by Richter) has plurality of

sidewall openings expandable to allow deployment of a stent. However, Fischell discloses a stent structure that incorporates a plurality of sidewall openings for deploying a stent through (12, Fig. 2 and Figs. 4a-4d). Claim 66: the openings are I shaped (Fig. 2). With respect to claims 67 and 68 there are first slots (12) that are larger than second slots (11) wherein the opening for deploying the third stent is a first slot and the slot would be aligned with the bifurcation (Fig. 4a-4d). Claim 79 and 80: the plurality of openings is expandable to a diameter substantially equal to an expanded diameter of at least on of the first, second or third stents. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the cell structure of Fischell into the Richter stent and the modified delivery device of Chermoni such that the first and second stent both comprises the plurality of sidewall openings, as in claim 72, in order to achieve the advantage of easily locating the sidewall opening at the branch for delivering a branch stent (Fischell C1:L10-25).

23. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Poncet, Richter and Brucker as applied to claims 53 and 64 above and further in view of Shaknovich (US 5,807,398).

24. Modified Chermoni does not explicitly state the step of dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. However, Chermoni does contemplate the multiple steps of balloon angioplasty and stent delivery when discussing prior art (Para [003]). Shaknovich discloses a single catheter multiple stent delivery device similar to

Chermoni modified by Brucker and explicitly discloses using the expandable member to pre-dilate a vessel prior to stent delivery in order to provide an adequate passageway for the delivery catheter (C 12: 20-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the step of dilating a lesion prior to stent delivery into the method disclosed by Chermoni modified by Brucker. Pre-dilating the vessel prior to stent delivery is old and well known in the art and provides the advantage of increasing the diameter of the passage to allow the catheter to get through.

Response to Arguments

25. Applicant's arguments regarding priority, filed 12/29/09, have been fully considered but they are not persuasive.

26. Applicant states that there is no reasonable basis to support the notion that one skilled in the art would not realize that the delivery catheter in the'713 application could be used to perform the method in the '713 method without intermediate removal of the catheter. Applicant is directed to the argument provide under Priority at the beginning of the action.

27. The disclosure of the '713 application is broader than the invention that is claimed in the instant application and therefore it does not anticipate the claims of the current application. The '713 application provides two separate pieces of information and requires one of skill to combine these teachings using obviousness rationale (as stated by applicant in remarks and repeated above). Examiner asserts that if one needs

to rely on obviousness rationale to show support for the claimed invention, then it should be clear that the '713 application does not provide adequate support for the claimed invention of the instant application.

28. Applicant's arguments with respect to claim 53-78 with respect to prior art have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/15/10